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ATTENTION: Commissioner for Patents
FIRM/CO. NAME: USPTO
FAX NO: (571) 273-8300
ART/UNIT NO: 3771
FROM: Guy Tucker
DATE: May 14, 2008
APPLICATION NO: 10/821,624
OUR REFERENCE NO: NK.197.00

TOTAL NUMBER OF PAGES 13 (INCLUDING COVER PAGE)

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BUSINESS PHONE: (415) 538-1555 FACSIMILE NO.: (415) 538-8380

MESSAGE:

Attached please find an Appeal Brief in the above referenced application.

Thank you for your attention,

Leslie Mills
for: Guy Tucker

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Dunkley et al.	Group No: 3771	RECEIVED CENTRAL FAX CENTER MAY 14 2008					
Application No: 10/821,624	Examiner: Shumaya B. Ali						
Confirmation No: 8935	Attorney Docket No: NK.197.00						
Filed: April 9, 2004	May 14, 2008						
Title: AEROSOLIZATION APPARATUS WITH CAPSULE PUNCTURE ALIGNMENT GUIDE	San Francisco, California 94107						
Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Extension of Time						
Papers Enclosed	Extension (Months)	Extension Fee					
<input checked="" type="checkbox"/> Appeal Brief		Large Entity	Small Entity				
<input type="checkbox"/> Declaration		\$120.00	\$60.00				
<input type="checkbox"/> Drawings		\$480.00	\$230.00				
<input type="checkbox"/> Supplemental Information Disclosure Statement	\$1050.00	\$525.00					
<input type="checkbox"/> PTO-1449 Form	Total \$ 0.00						
<input type="checkbox"/> Citations							
<input type="checkbox"/> Terminal Disclaimer							
<input type="checkbox"/> Postcard for Return							
<input checked="" type="checkbox"/> Applicant believes that no extension of term is required. However, this conditional petition is being made in case applicant has inadvertently overlooked the need for a petition for extension of time.							
Fees for Extra Claims							
	Claims remaining after amendment	Highest number previously paid for	Number Extra	Rate		Additional Fee	
Total Claims	11	46	0	Large Entity	Small Entity		
Independent Claims	2	5	0	\$50.00	\$25.00	\$0.00	
Multiple Dependent Claims				\$210.00	\$105.00	\$0.00	
Supplemental Information Disclosure Statement				\$370.00	\$185.00	\$0.00	
						Total	\$0.00
Fee Payment				Fee Deficiency			
Extension Fees	\$ 0.00			<input checked="" type="checkbox"/> If any additional extension and/or fee is required, please charge Deposit Account No. <u>10-0258</u> , and/or			
Fees for Extra Claims	\$ 0.00			<input checked="" type="checkbox"/> If any additional fee for claims is required, please charge Deposit Account No. <u>10-0258</u> .			
Appeal Brief Fee	\$510.00						
Total	\$510.00						
<input type="checkbox"/> Attached is check no. _____ in the sum of \$ _____. <input checked="" type="checkbox"/> Please charge Deposit Account No. <u>10-0258</u> in the sum of <u>\$510.00</u> .				Please direct telephone calls to: Guy V. Tucker at (415) 538-1555. Please send all correspondence to: Guy V. Tucker Janah & Associates, P.C. 650 Delancey Street, Suite 106 San Francisco, CA 94107-2001			
CERTIFICATE OF TRANSMISSION (37 C.F.R. 5.18a): <i>(Facsimile transmitted to the U.S.P.T.O. via Fax No. (511) 273-8300)</i> I hereby certify that this correspondence is being electronically filed, on the date shown below. By: <u>Leslie Mills</u> Date: May 14, 2008				Respectfully Submitted, By: <u>Guy V. Tucker</u> Date: May 14, 2008 Guy V. Tucker Registration No. 45,302			

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In re Application of: Dunkley et al.	Group Art Unit: 3771
Application No: 10/821,624	Examiner: Ali, Shumaya B
Confirmation No: 8935	Attorney Docket No: NK.197.00
Filed: April 9, 2004	
Title: AEROSOLIZATION APPARATUS WITH CAPSULE PUNCTURE ALIGNMENT GUIDE	May 14, 2008 San Francisco, California 94107

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of October 16, 2007, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

Certificate of Transmission	
I hereby certify that this correspondence is being submitted by facsimile at (571-273-8300), on the date shown below.	
By:	 Leslie Mills
Date: <u>May 14, 2008</u>	

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(1) Real Party in Interest

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 201 Industrial Road; San Carlos, California 94707.

(2) Related Appeals and Interferences

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) Status of Claims

Claims 20-28, 31 and 32 are presently pending in the case. Claims 1-19, 29, 30, 33 and 34 have been cancelled without prejudice or disclaimer. Claims 21-26 are withdrawn from consideration until such time as the generic claim from which they depend is determined to be allowable. Claims 20, 27, 28, 31 and 32 have been finally rejected. The rejection of each of claims 20, 27, 28, 31 and 32 is hereby appealed.

(4) Status of Amendments

An After Final Amendment was filed on March 14, 2008. In an Advisory Action dated March 18, 2008, the Examiner indicated that the After Final Amendment would be entered for purposes of appeal. Accordingly, all amendments made during prosecution of the case are believed to be due entry.

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(5) Summary of the Claimed Subject Matter

As claimed in claim 20, an aerosolization apparatus according to one version of the invention comprises a housing (105) defining a chamber (110) having one or more air inlets (115). The chamber is sized to receive a capsule (125) which contains an aerosolizable pharmaceutical formulation. The apparatus also comprises a puncturing mechanism (130) within the housing. The puncturing mechanism comprises an alignment guide (132) and a puncture member (135), wherein the alignment guide comprises a surface (133) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening in the capsule. The surface (133) comprises one or more protrusions (300 and variations discussed on page 11 lines 19-30) for contacting the capsule. The apparatus also comprises an end section (140) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule.

As claimed in claim 31, a method of providing access to an aerosolizable pharmaceutical formulation according to one version of the invention comprises providing a capsule (125) containing an aerosolizable pharmaceutical formulation; contacting the capsule with the surface (133) of an alignment guide (132), the surface comprising one or more protrusions (300 and variations discussed on page 11 lines 19-30) for contacting the capsule; and advancing a puncture member (135) through the wall of the capsule to create an opening in the capsule.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant requests review of the Examiner's following grounds of rejection:

Claims 20, 27 and 28 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 4,069,819 to Valentini et al (hereinafter Valentini et al).

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Claims 31 and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Valentini et al in view of U.S. Patent Application US 2003/0000523 to Citterio (hereinafter Citterio).

(7) Argument

Appellant believes each of claims 20, 27, 28, 31 and 32 are improperly rejected and are therefore allowable for the following reasons.

The rejection of independent claim 20 under 35 U.S.C. §102 is improper

Valentini et al does not anticipate independent claim 20. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 20 is to an aerosolization apparatus comprising, inter alia, a puncturing mechanism that comprises an alignment guide having a surface adapted to contact a capsule while a puncture member is advanced into the capsule, and wherein the surface comprises one or more protrusions for contacting the capsule. This positively recited feature is not disclosed by Valentini et al. More specifically, Valentini et al does not disclose an alignment guide having a contact surface comprising one or more protrusions for contacting a capsule. The contact surface at the end of element L of Valentini et al contains no protrusions. Since Valentini et al does not disclose each and every feature set forth in claim 20, it does not anticipate the claim.

The Examiner's comments do not serve to establish Valentini et al as an anticipatory reference with regard to claim 20. On page 9 of the Final Office Action of October 16, 2007, the Examiner seems to be taking the position that the forward end of the contact surface can be considered to be a protrusion of the type claimed. However, this is an improper distortion of the reference and its teachings and does not satisfy the

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limitations positively set forth in claim 20. The contact surface of Valentini et al is the angled surface on which the capsule rests during puncturing of the capsule. There are no protrusions extending from *that* surface in Valentini et al. To say the forward end of the angled surface is a "protrusion" is no different than saying a flat tabletop comprises protrusions because of its four edges. Furthermore, the Examiner's characterization is improper because the forward end of the surface of Valentini et al does not serve to satisfy the claim limitations in that the forward end does not contact the capsule. Moreover, as required by the claim 20, the contact surface is defined as the surface that contacts the capsule during the puncturing of the capsule. As can be seen in Figure 5 of Valentini et al when the holes in the capsule are aligned with the puncturing members, the portion of the surface that contacts the capsule does not comprise any protrusions. For at least these reasons, the Examiner's position is untenable, and Valentini et al does not anticipate claim 20.

Appellant requests reversal of the rejection of claim 20 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 27 and 28 which depend from claim 20 and are not anticipated by Valentini et al for at least the same reasons as claim 20.

The rejection of independent claim 31 under 35 U.S.C. §103(a) is improper

Valentini et al and Citterio do not render claim 30 unpatentable. Claim 30 is to a method of providing access to an aerosolizable pharmaceutical formulation, the method comprising, *inter alia*, contacting a capsule with the surface of an alignment guide, the surface comprising one or more protrusions for contacting the capsule, and advancing a puncture member through the wall of the capsule to create an opening in the capsule. Valentini et al does not teach contacting a capsule with a surface comprising one or more protrusions, as discussed above. Citterio is cited by the Examiner for allegedly teaching a removable end section. Thus, Citterio does not teach, nor is it alleged to teach, that which Valentini et al lacks with regard to meeting the limitations of claim 30, i.e. a surface with a protrusion, as claimed in claim 30. Therefore, Citterio fails to make

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up for the deficiencies of Valentini et al. Accordingly, Valentini et al and Citterio fail to disclose or suggest all positively recited limitations, and the Examiner has failed to establish a *prima facie* case of obviousness under 35 USC 103(a).

For at least these reasons, claim 30 is not properly rejectable under 35 USC §103(a) as being unpatentable over Valentini et al and Citterio. In addition, a modification that would result in the invention claimed in claim 30 is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no showing or allegation that any such modification could be applied, with a reasonable likelihood of success, to Valentini et al. Furthermore, there is no evidence to suggest that this is a situation where the ordinary artisan would have seen the benefit of making the modification. Moreover, Appellant has unexpectedly found that by providing the protrusion, the efficiency of the device is increased and the lifetime of the device is extended, as discussed on page 11 lines 19-30 of the specification. Thus, claim 30 is allowable over the references cited for these additional reasons.

Appellant requests reversal of the rejection of claim 30 under 35 U.S.C. §103(a). In addition, Appellant requests withdrawal of the rejection of claim 31 which depends from claim 30 and is not rendered unpatentable by Valentini et al and Citterio for at least the same reasons as claim 30.

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Conclusion

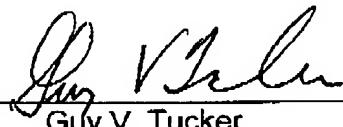
Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: 14 MAY 2008

By: 
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Reg. No. 45,302

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(8) Claims Appendix

20. An aerosolization apparatus comprising:
a housing defining a chamber having one or more air inlets, the chamber being sized to receive a capsule which contains an aerosolizable pharmaceutical formulation;
a puncturing mechanism within the housing, the puncturing mechanism comprising an alignment guide and a puncture member, wherein the alignment guide comprises a surface adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening in the capsule, and wherein the surface comprises one or more protrusions for contacting the capsule; and
an end section associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule.

27. An aerosolization apparatus according to claim 20 wherein surface comprises a passageway and wherein the puncture member slides within the passageway.

28. An aerosolization apparatus according to claim 20 wherein the inlet is shaped to create a swirling airflow within the chamber.

31. A method of providing access to an aerosolizable pharmaceutical formulation, the method comprising:
providing a capsule containing an aerosolizable pharmaceutical formulation;
contacting the capsule with the surface of an alignment guide, the surface comprising one or more protrusions for contacting the capsule; and
advancing a puncture member through the wall of the capsule to create an opening in the capsule.

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32. A method according to claim 31 wherein the puncture member is advanced through a passageway in the surface.

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(9) Evidence Appendix

none

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(10) Related Proceedings Appendix

none